

**PRELIMINARY AMENDMENT**

25. (new) A method of producing a product according to a process essentially controlled by a set of  $n$  parameters  $X_i$  affecting a set of  $k$  properties  $Y_j$  characterizing the product, said method comprising:

- i. assigning values to a set of  $k$  property weights  $w_j$  representing relative importance of said properties  $Y_j$  for the characterization of said product;
- ii. establishing property behavior mathematical relations giving an estimated property  $Ye_j$  for each said property  $Y_j$  in terms of said parameters  $X_i$  from given parameter data and associated property data;
- iii. using said property weights  $w_j$  to establish a goal function in terms of property weighted deviations between the estimated properties  $Ye_j$  and corresponding specified goal values for said properties  $Y_j$ ;
- iv. minimizing the goal function to generate a set of  $n$  optimal parameter values for said parameters  $X_i$ ; and
- v. using said set of optimal parameter values in said process to produce said product.

26. (new) A method according to claim 25, wherein said product is a composition of matter, said set of optimal parameter values characterizing an optimal formulation for the composition.

27. (new) A method according to claim 26, wherein said product is a pharmaceutical product, said set of optimal parameter values characterizing an optimal formulation for the pharmaceutical product.

28. (new) A method according to claim 25, wherein the values for said property weights  $w_j$  are obtained using an algorithm based on an analytic hierarchy process.

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29. (new) A method according to claim 28, wherein said given property data are obtained through a number  $l$  of experimental runs of said process using said given parameter data, each said run using a distinct set of values for said given parameter data.
30. (new) A method according to claim 29, wherein said number of experimental runs of said process each uses a selected distinct set of values for said parameters  $X_i$ , covering substantially all extreme values within a chosen range of values for each one of said parameters  $X_i$ , wherein  $l$  is at least equal to  $n + 1$  and is substantially less than a number used in the Fractional Factorial Matrix method.
31. (new) A method according to claim 27, wherein the values for said property weights  $w_j$  are obtained using an algorithm based on an analytic hierarchy process.
32. (new) A method according to claim 31, wherein said given property data are obtained through a number  $l$  of experimental runs of said process using said given parameter data, each said run using a distinct set of values for said given parameter data.
33. (new) A method according to claim 32, wherein said number of experimental runs of said process each uses a selected distinct set of values for said parameters  $X_i$ , covering substantially all extreme values within a chosen range of values for each one of said parameters  $X_i$ , wherein  $l$  is at least equal to  $n + 1$  and is substantially less than a number used in the Fractional Factorial Matrix method.
34. (new) A method according to claim 25, wherein said goal function is expressed as follows:

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$$G(X_1, \dots, X_n) = \sum_{j=1}^k w_j^2 (Y_j - O_j)^2$$

wherein  $O_j$  are said specified goal values for said properties  $Y_j$ .

35. (new) A method according to claim 34, wherein said minimizing step is performed by successive iterations of:

$$G(X_1, \dots, X_n) = \sum_{i=1}^k [f_i(X_1, \dots, X_n)]^2.$$

36. (new) A method according to claim 35, wherein said goal function is minimized according to one or more specified ranges  $(a_i, b_i)$  wherein  $a_i < X_i < b_i$  for one or more of said optimal parameter values.

37. (new) A method according to claim 25, further comprising the steps of:  
performing experimentally said process using said set of optimal parameters values to obtain corresponding experimental values for said properties  $Y_j$ ;  
ranking said set of optimal parameters values over predetermined alternative sets of parameters values for said  $X_i$ .

38. (new) A method according to claim 37, wherein said ranking step is performed using an algorithm based on an analytic hierarchy process.

39. (new) A method according to claim 37, further including the step of:  
incorporating said set of optimal parameters values and said corresponding experimental values for said properties  $Y_j$  respectively into said given parameter and associated property data;  
repeating said steps ii) to iv) to generate a new set of optimal parameters values for said parameters  $X_i$ .

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40. (new) A method of producing a product using optimized process parameter values, said process being essentially controlled by a set of  $n$  parameters  $X_i$  characterizing a formulation for said product, said parameters  $X_i$  affecting a set of  $k$  properties  $Y_j$  characterizing the product, said method comprising:

- a) conducting a number of  $l$  of experimental runs of said process each using a selected distinct set of values for said parameters  $X_i$  covering substantially all extreme values within a chosen range of values for each one of said parameters  $X_i$ , wherein  $l$  is at least equal to  $n + 1$  and is substantially less than a number used in the Fractional Factorial Matrix method;
- b) measuring values for said properties  $Y_j$  characterizing the product in each of said  $l$  experimental runs, whereby parameter data and associated property data are obtained from said selected distinct set of values for said parameters  $X_i$  and said measured values for said properties  $Y_j$ , respectively;
- c) determining an importance of said properties  $Y_j$  for the characterization of said product, comparing said importance of said properties  $Y_j$  relative to one another, and assigning values to a set of  $k$  property weights  $w_j$  representing a relative importance of said properties  $Y_j$  for the characterization of said product;
- d) calculating a set of optimal parameter values for said parameters  $X_i$  using said measured values for said properties  $Y_j$  and said assigned values of said set of  $k$  property weights  $w_j$ ; and
- e) producing said product using said optimized process parameter values  $X_i$  calculated in the previous step.

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41. (new) A method according to claim 40, wherein said product is a pharmaceutical product, and said process is a formulation of said product.

42. (new) A method according to claim 41, wherein said step of calculating comprises:  
establishing property behavior mathematical relations giving an estimated property  $Y_{e_j}$  for each said property  $Y_j$  in terms of said parameters  $X_i$  from said parameter data and associated property data;  
using said property weights  $w_j$  to establish a process goal function in terms of property weighted deviations between the estimated properties  $Y_{e_j}$  and corresponding specified goal values for said properties  $Y_j$ ; and  
minimizing the process goal function to generate a set of optimal parameter values for said parameters  $X_i$ .

43. (new) A method according to claim 42, wherein the values for said property weights  $w_j$  are obtained by an algorithm based on an analytic hierarchy process.

44. (new) A method according to claim 40, wherein  $l = n + 1$ .

45. (new) A method according to claim 42, wherein  $l = n + 1$ .

46. (new) A method according to claim 43, wherein  $l = n + 1$ .

47. (new) A method according to claim 41, wherein said goal function is expressed as follows:

$$\text{i. } G(X_1, \dots, X_n) = \sum_{j=1}^k w_j^2 (Y_{e_j} - O_j)^2$$

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wherein  $O_j$  are said specified goal values for said properties  $Y_j$ .

48. (new) A method according to claim 47, wherein said minimizing step is performed through successive iterations.

49. (new) A method according to claim 48, wherein said goal function is minimized according to one or more specified ranges  $(a_i, b_i)$  wherein  $a_i < X_i < b_i$  for one or more of said optimal parameters values.

50. (new) A method according to claim 41, further comprising the steps of:

- f) performing experimentally said process using said set of optimal parameters values to obtain corresponding experimental values for said properties  $Y_j$ ;
- g) ranking said set of optimal parameters values over predetermined alternative sets of parameters values for said  $X_i$ .

51. (new) A method according to claim 50, wherein said ranking step is performed through an algorithm based on an analytic hierarchy process.

52. (new) A method according to claim 41, further including the steps of:

- h) incorporating said set of optimal parameters values and said corresponding experimental values for said properties  $Y_j$  respectively into said given parameter and associated property data;
- i) repeating said steps a), b) and d) to generate a new set of optimal parameters values for said parameters  $X_i$ .